

Diagnostic Microbiology Specimen Submission Guidelines

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General Information

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Address: Kansas Department of Health and Environmental Laboratories

6810 SE Dwight Street Topeka, Kansas 66620

Phone Number: (785) 296-1620 **Fax Number:** (785) 296-1641

Hours of Operation:

Open Monday through Friday 8:00am to 5:00pm.

KHEL does not perform testing and observes the following holidays:

New Year's Day (January 1*)

Martin Luther King, Jr, Day (3rd Monday of January)

Memorial Day (Last Monday of May)

Independence Day (July 4*)

Labor Day (1st Monday of September)

Veteran's Day (*November 11**)

Thanksgiving (4th Thursday and Friday of November)

Christmas Day (December 25*)

*When a holiday falls on Saturday, it is observed on the preceding Friday. When a holiday falls on Sunday, it is observed on the following Monday.

Website: http://www.kdheks.gov/labs/index.html

The purpose of this manual is to provide a ready reference to our clients and to assist them in obtaining laboratory services as efficiently as possible.

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The policy of the Kansas Department of Health and Environmental Laboratories (KHEL) is to provide microbiology diagnostic support to county and state agencies. In addition, KHEL serves as a reference microbiology laboratory to hospital and independent clinical laboratories in order to

confirm their atypical results from cultures and clinical specimens. This information is also used as part of the Kansas Department of Health and Environment (KDHE) Epidemiology and Public Health Informatics infectious disease surveillance program. The KDHE Infectious Disease Epidemiology and Response program conducts the infectious disease surveillance and outbreak investigations and provides subject matter expertise to local health departments, physicians, veterinarians, and the general public.

KDHE reporting requirements can be found at http://www.kdheks.gov/epi/disease_reporting.html. This report identifies diseases which must be reported to the state and which isolates must be submitted to the laboratory. Please follow packaging and shipping guidelines found in this manual, or on our website at http://www.kdheks.gov/labs/packaging_and_shipping.html to submit specimens to KHEL.

KHEL provides specimen collection materials and mailers free of charge for the purpose of outbreak investigation or for enforcement of K.A.R 28-1-6, which restricts or excludes those who work in food handling, patient care, and any occupation involving the care of young children and the elderly, as well as those who attend a child care facility or a family day care home. Stool specimens sent to KHEL can be tested for parasites (including *Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica*, and *Giardia lamblia*); enteric bacteria (including *Campylobacter, Clostridium difficile, Plesiomonas shigelloides, Salmonella, Yersinia enterocolitica, Vibrio,* and *Vibrio cholerae*; Diarrheagenic *E. coli*/Shigella (including Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) *It/st*, Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*, *E. coli* O157, *Shigella*/Enteroinvasive *E. coli* (EIEC)); and viruses (including Adenovirus F40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, and Sapovirus).

Further information regarding specimen collection materials, mailing containers and *Requisition for Laboratory Specimen Kits and Supplies* form is located in this manual. Supplies ordered from KHEL are to be used ONLY to submit specimens to KHEL. All requisitions for specimen kits and supplies for specimen submission can be request by mailing, faxing, or calling the KHEL Customer Service unit in Topeka:

Kansas Department of Health and Environmental Laboratories

ATTN: Customer Service 6810 SE Dwight Street Topeka, Kansas 66620 Phone: (785) 296-1623 Fax: (785) 296-1641

http://www.kdheks.gov/labs/cust_serv/download/specimen_kit_request_form.pdf

Please request specimen collection materials and mailers before they are required as the expected turnaround time per order is **FIVE** business days. Most materials do have a limited shelf life; therefore, only order what will be used before the expiration date. Please do not use expired kits or any kits in which the media has changed characteristics. Dispose of the media properly and order replacement supplies.

The Clinical Laboratory Improvement Act (CLIA) regulations require a unique patient identifier on both the specimen container and the *KDHE Universal Laboratory Specimen Submission Form* (Health). For example, each specimen must be properly labeled with at least the barcode label from the *KDHE Universal Laboratory Specimen Submission Form* (Health).

KHEL specimen submission guidelines are referenced from the guiding principles set forth by the Clinical and Laboratory Standards Institute (CLSI) and the Centers for Disease Control and Prevention (CDC).

Specimen Rejection Guidelines

KHEL currently has the following policy for rejection of laboratory specimens and/or requested examinations. KHEL will NOT examine clinical/reference specimens if the following circumstances exist:

- The patient identifier on the specimen did not match the identifier on the submission form, or there was no identification on the specimen.
- The quantity of specimen was not sufficient for examination.
- The quality of specimen was not sufficient for examination.
- The quantity of specimen did not meet the specimen collection guidelines.
- The transit time for the specimen exceeded the maximum allowable time frame from the time of collection to receipt by the laboratory.
- The specimen was broken or leaked in transit.
- Specimen was submitted in an improper or expired container, transport media or preservative.
- Blood specimens submitted for diagnostic microbiological analysis were hemolyzed or contaminated.
- Reference cultures were mixed or contaminated.
- Test request deemed unnecessary by the KDHE Infectious Disease Epidemiology and Response Program and/or the Kansas Tuberculosis Control Program.

Exceptions to this policy will be considered due to extenuating circumstances; however, final approval to make an exception can only be made by the Laboratory Director, Laboratory Deputy Director, Health Section Chief, Diagnostic Microbiology Unit Manager, and/or Diagnostic Microbiology Technical Supervisor.

Specimen Collection Guidelines

FedEx Overnight and 2Day and UPS Next Day Air and Ground services are encouraged as the delivery times are guaranteed by the carriers. The use of a commercial carrier service is also encouraged if specimens are delivered to KHEL within the window of the collection date and time. The use of USPS is discouraged for all clinical specimens for mycobacterium testing as the delivery times are not guaranteed by the carrier.

*All clinical specimens for mycobacterium testing must be received by KHEL within 7 days of collection date and time. Specimen collection is encouraged Monday through Thursday with delivery to KHEL Monday through Friday by 10:00am. Specimen collection is not encouraged on Fridays or the day before a holiday (see page 2 for list of observed state holidays). All clinical specimens received by 10:00am Monday through Friday will be tested the same day. Specimens received after 10:00am Monday through Friday will be tested the following business day.

Abscess

- Mycobacterium Testing*
 - Remove surface exudate by wiping with sterile saline or 70% ethanol. Collect fluid abscess material with syringe and/or remove tissue aseptically. For open lesions/abscesses, aspirate material from under the margin of the lesion/abscess. Remove tissue aseptically. Collect tissue in 5-10mL sterile saline in a sterile, dry, leak-proof container, such as a 50mL conical tube.
 - o Must be received by KHEL by 10:00am within 7 days of collection date and time.

Blood

- Mycobacterium Testing*
 - Aseptically collect 10mL of whole blood in 10mL yellow-top collector tube containing sodium polyanethole sulfonate (SPS), or green-top collector tube containing heparin. Minimum volume for adults is 5mL and for children is 1mL.
 - o Must be received by KHEL by 10:00am within 7 days of collection date and time.
- QuantiFERON-TB Gold Testing
 - Within 16 hours of collection, incubate tubes upright at 37°C for 16 24 hours.
 - Must be received by KHEL within 72 hours of incubation.

Bodily Fluids (abdominal, bile, joint, peritoneal, pericardial, pleural, synovial, thoracentesis)

- Mycobacterium Testing*
 - Aseptically collect 5-10mL or more of fluid in a sterile, dry, leak-proof container, such as a 50mL conical tube container. Do not submit a swab dipped in fluid to KHEL.
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Bronchoalveolar Lavage, Brush, or Wash

- Mycobacterium Testing*
 - Collect 5-10mL of washing or aspirate in a sputum trap and place brush in sterile, dry, leak-proof container, such as a 50mL conical tube, with up to 5mL of sterile saline.

Must be received by KHEL by 10:00am within 7 days of collection date and time.

CSF

- Mycobacterium Testing*
 - Aseptically collect 5mL, 10mL optimal, of cerebrospinal fluid in a sterile, dry, leakproof container, such as a 50mL conical tube.
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Isolate

- Enteric Confirmation (Salmonella, Shigella, STEC)
 - Pure isolated colonies (<48 hours old) in appropriate tubed media or broth, such as GN broth. Seal liquid media with parafilm or other appropriate barrier film. Do not send isolate specimens on agar plates.
 - Must be received by KHEL within 21 days of collection.
- Mycobacterium Testing
 - Pure isolated colonies in appropriate tubed media or broth, such as Lowenstein Jensen slant or Middlebrook 7H10 or 7H11 slant. Seal liquid media with parafilm or other appropriate barrier film. Do not send isolate specimens on agar plates.
 - Must be received by KHEL within 21 days of collection.

Sputum

- Mycobacterium Testing*
 - Instruct patient to cough deeply to produce a 5-10mL lower respiratory specimen (not postnasal fluid) in to sterile, dry, leak-proof container, such as a 50mL conical tube.
 - Replication limits are three consecutive sputum specimens collected in 8 24 hour intervals (24 hours when possible).
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Stool

- Enteric Screening Testing
 - Collect a quarter sized amount of stool and transfer into a Cary-Blair transport medium vial.
 - Must be received by KHEL within 4 days of collection for molecular testing.
- Enteric Confirmation (Salmonella, Shigella, STEC)
 - Collect a quarter sized amount of stool and transfer into a Cary-Blair transport medium vial.
 - Must be received by KHEL within 7 days of collection.
- Mycobacterium Testing*
 - Collect 5-10mL of stool in a sterile, dry, leak-proof container, such as a 50mL conical tube.
 - o Must be received by KHEL by 10:00am within 7 days of collection date and time.
- Ova & Parasite Testing
 - o It is recommended that three O and P collection kits be submitted for each patient within a ten day period, at least one day between collections.
 - The examination of a single stool specimen is only about 50% accurate in the detection of parasites, especially intestinal protozoa.

- Intestinal protozoa are shed in the stool on a cyclic basis. It is generally accepted that this time frame is approximately 10 days, so if specimens are collected too close together, sampling may occur at a low point in the cycle and the organisms may be missed. By collection specimens over a wider time frame, days with heavier shedding may be sampled as well.
- Collect a quarter sized amount of stool and transfer into both 10% formalin and polyvinyl alcohol (PVA) vials.
- Must be received by KHEL within 7 days of collection.

Tissue/Lymph Node

- Mycobacterium Testing*
 - Aseptically collect during surgery or cutaneous biopsy procedure in a sterile, dry, leak-proof container, such as a 50mL conical tube. Add 5-10mL sterile saline to tissue for transport. Do not submit a swab dipped in fluid to KHEL. If a sterile swab is used, vortex swab in 2-3mL sterile saline and submit in a sterile, dry, leak-proof container, such as a 50mL conical tube.
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Urine

- Mycobacterium Testing*
 - Collect 5-10mL of urine in a sterile, dry, leak-proof container, such as a 50mL conical tube. A specimen from first thing in the morning is preferred. Do not use preservatives.
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Wound

- Mycobacterium Testing*
 - Remove surface exudate by wiping with sterile saline or 70% ethanol. Collect fluid wound material with syringe and/or remove tissue aseptically. For open wounds, aspirate material from under the margin of the wound. Remove tissue aseptically. Collect tissue in 5-10mL sterile saline in a sterile, dry, leak-proof container, such as a 50mL conical tube.
 - Must be received by KHEL by 10:00am within 7 days of collection date and time.

Specimen Shipping Guidelines

All infectious material must be classified as either Category A (UN2814, Infectious substances, affecting humans, 6.2) or Category B (UN3373) and must be transported to KHEL according to appropriate IATA (International Air Transportation Association www.iata.org), USPS (United States Postal Service www.usps.com) and DOT (U.S. Department of Transportation www.transportation.gov) shipping regulations. All infectious material must be triple-packaged to protect against breakage and/or leakage during transportation. All specimens and isolates must be in leak proof containers with properly fastened screw caps. Isolates in liquid media are to be sealed with parafilm or other appropriate barrier film. Shipments that meet the definition for 'Category A' infectious substances as defined by federal regulations require additional packaging and labeling.

Package Marking and Label Requirements

- Category A
 - Proper shipping name and UN2814 label
 - Shipper or consignee identification
 - o Infectious substance label 172.432
 - Orientation arrows (as applicable)
- Category B
 - o Proper shipping name and UN3373 label
 - Name and telephone number of responsible person
 - May be placed on separate document such as air waybill
 - Orientation arrows (as applicable)

Shipping Documents

- Category A
 - Identification number
 - Proper shipping name
 - Hazard class/division
 - Number of packaging group
 - Type of package/unit of measure (QTY)
 - Dangerous Goods Shipper's Declaration
 - Emergency response telephone number
- Category B
 - No shipping papers required unless not under exception. Substances which are unlikely to cause disease in humans or animals or do not contain infectious substances are not subject to the Regulations unless they meet criteria for inclusion in another class.

*All Category A shipments require a fiberboard infectious disease box with a corrugated divider insert, a red-topped secondary container (95kPa container), bubble wrap for padding, an absorbent pad, and a signed and completed Dangerous Goods Shipper's Declaration. All Category A Infectious Disease shippers requisitioned from KHEL will include a checklist for completing the Dangerous Goods Shipper's Declaration. The checklist can be found at the following link http://www.kdheks.gov/labs/downloads/Checklist_for_Shippers.pdf

Reminder: E. coli O157:H7 and STEC positive broth and isolates are 'Category A'. Shipments that meet the definition for 'Category A' infectious substances as defined by federal regulation require additional packaging/labeling.

Submit all specimens to:

Kansas Department of Health and Environmental Laboratories 6810 SE Dwight Street Topeka, Kansas 66620 (785) 296-1620

Abscess

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.

Blood

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label.
 - Do not refrigerate or freeze blood specimens.
- QuantiFERON-TB Gold Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label. Indicate "QFT" on shipping label.
 - Do not refrigerate or freeze blood specimens.

Bodily Fluids (abdominal, bile, joint, peritoneal, pericardial, pleural, synovial, thoracentesis)

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.

Bronchoalveolar Lavage, Brush, or Wash

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a *Biological Substance*, *Category B (TB)* shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.

CSF

- Mycobacterium Testing
 - Ship as soon as possible at room temperature in a TB mailer with a *Biological Substance*, Category B (TB) shipping label.
 - Do not refrigerate or freeze the specimen.

Isolate

- Enteric Confirmation (Salmonella, Shigella)
 - Ship at room temperature in a Bacterial Isolate mailer with a Biological Substance,
 Category B Enteric/Misc Bacterial shipping label.
- STEC Confirmation
 - Ship at room temperature in a Category A mailer*.
- Mycobacterium Testing
 - Ship at room temperature in a Category A mailer*.

Sputum

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B Sputum (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.

Stool

- Enteric Screening Testing
 - Ship cold (ideal) or at room temperature in an Enteric with Cary Blair mailer with a Biological Substance, Category B – Enteric/Misc Bacterial shipping label.
- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.
- Ova & Parasite Testing
 - Ship at room temperature in a Parasite with Formalin and PVA mailer with a Biological Substance, Category B – Feces (Parasite) shipping label.

Tissue/Lymph Node

- Mvcobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B Sputum (TB) shipping label.

Urine

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B Sputum (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.

Wound

- Mycobacterium Testing
 - Ship at room temperature in a TB mailer with a Biological Substance, Category B (TB) shipping label.
 - If transport is delayed by more than one hour from the date and time of collection, the specimen must be refrigerated.